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**Janssen Submits New Drug Application to U.S. Food and Drug Administration
for the First Darunavir-Based Single Tablet Regimen for the Treatment of HIV-1**

Janssen seeks approval for investigational regimen that aims to combine efficacy, durability, and the high genetic barrier to resistance of darunavir with the renal and bone safety profile of emtricitabine/tenofovir alafenamide in a once daily pill

TITUSVILLE, NJ, September 25, 2017 – Janssen Research & Development, LLC today announced the submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for darunavir 800mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg (D/C/F/TAF), a complete, once daily regimen being investigated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients aged 12 years and older. If approved, D/C/F/TAF will be the only complete regimen to deliver the potential adherence advantages of a single tablet regimen (STR) with the high genetic barrier to resistance of darunavir and demonstrated safety profile of TAF. Cobicistat, emtricitabine and tenofovir alafenamide are from Gilead Sciences, Inc.

The filing is based on results from two pivotal Phase 3 studies:

- EMERALD, a 48-week, non-inferiority study evaluating the efficacy and safety of switching to D/C/F/TAF (n=763) versus continuing on a boosted protease inhibitor (PI) plus F/TDF regimen (n=378).
- AMBER, a 48-week non-inferiority study evaluating the efficacy and safety of D/C/F/TAF (n=362) versus control of a DRV/C+F/TDF (n=363) in treatment-naïve patients.

To date, Phase 3 D/C/F/TAF trials demonstrate high rates of virologic suppression and no treatment-emergent DRV or TAF resistance among both treatment-naïve adult patients and virologically suppressed adult patients who switched regimens. EMERALD 48-week data will be presented at ID Week 2017, October 4-8 in San Diego, California, and AMBER 48-week data will be presented at the European AIDS Conference, October 25-27 in Milan, Italy.

“This filing marks an important milestone in continuing to address the needs of individuals living with HIV who struggle with adherence and the associated risk of developing medication resistance,” said Richard Nettles, Vice President, Medical Affairs, Janssen. “If approved, this treatment will enable us to expand our promising portfolio of products for those living with HIV to include a medicine that for the first time brings together darunavir’s high genetic barrier to resistance with the safety profile of tenofovir alafenamide, in a once daily, single-pill dosing regimen.”

As part of a longstanding commitment to the research and development of treatments for HIV, Janssen has brought several important medicines to market to help improve the efficacy and tolerability of treatment. Today’s submission builds on this legacy and exemplifies Janssen’s ongoing dedication to those living with HIV.

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Notes to editors

On December 23, 2014, Janssen and Gilead Sciences Inc. amended a licensing agreement for the development and commercialization of a once-daily STR combination of darunavir and Gilead’s TAF, emtricitabine and cobicistat. Under the terms of the agreement, Janssen and its affiliates are responsible for the manufacturing, registration, distribution and commercialization of this STR worldwide.

About Janssen

At Janssen, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

About the AMBER clinical trial

The Phase 3 AMBER study is a randomized, active-controlled, double-blind, international, multi-center, parallel-group, non-inferiority study to evaluate efficacy and safety of D/C/F/TAF versus D/C with F/TDF in antiretroviral treatment-naïve HIV- 1 infected adults. The primary endpoint of the trial was the proportion of virologic responders, defined as HIV-1 RNA <50 copies /mL at Week 48 FDA snapshot approach, between arms, with a maximum allowable difference of 10%. 725 patients were randomized and treated as follows: 362 D/C/F/TAF; 363 control.

For more information on the clinical trials please visit: www.clinicaltrials.gov

About the EMERALD clinical trial

The Phase 3 EMERALD study is a randomized (2:1), open-label, international, multi-center, parallel-group, non-inferiority, 48-week study evaluating the efficacy and safety of switching to D/C/F/TAF versus continuing with a boosted PI plus F/TDF (control) in adult HIV-1 infected patients who are virologically suppressed (VL<50c/mL) for ≥2 months and had no more than one a viral load VL≥50c/mL over the last 12 months. The FDA-stipulated primary endpoint of the trial is the proportion of patients with cumulative virologic rebound (confirmed VL≥50c/mL or premature discontinuations with last VL≥50c/mL) through Week 48 (non-inferiority margin=4%). 1,141 patients were randomized and treated as follows: D/C/F/TAF (n=763); control (n=378).

For more information on the clinical trials please visit: www.clinicaltrials.gov

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the advantages and potential approval of a new treatment option for HIV-1. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," and the company's subsequent filings with the Securities and Exchange Commission. Copies of

these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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